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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bannon, et al.	Examiner:	Huynh, P.
Serial No.:	09/141,220	Art Unit:	1644
Filed:	August 27, 1998		
For:	METHODS AND REAGENTS FOR DECREASING CLINICAL REACTIONS TO ALLERGY		

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REPLY BRIEF UNDER 37 C.F.R. § 1.193

Appellant offers the present comments in Response to the Examiner's remarks in the Answer mailed February 9, 2005. Most of the Examiner's remarks in this Answer were restatements of previously-articulated positions, but some points were new; if a given item is not specifically discussed herein, then the Examiner has not presented new points of argument and/or Appellant relies on the arguments made in the Appeal Brief.

For ease of presentation, Appellant's comments in this Reply Brief are organized according to the headings and numbered issues presented in Appellant's Amended Brief submitted November 22, 2004 (the "Brief"). For the convenience of the Board, references to pages within the Examiner Answer are also included.

The deadline for filing a Reply Brief is April 9, 2005. Applicant thus submits that the present Reply Brief is timely filed on April 7, 2005.

Issues

Appellant recognizes and thanks the Examiner for withdrawing the rejections that were discussed under issues 5, 11 and 12 of the Brief (page 2 of the Examiner's Answer). Issues 1-4 and 6-10 of the Brief remain in dispute.

Grouping of Claims

The Examiner states that the claims of Groups A and B should stand and fall together for purposes of issue 1 (enablement) because the claims of Group B are species claims that fall within the scope of generic claims in Group A (page 4 of the Examiner's Answer). Appellant respectfully notes that, even if it is true that claims of Group B are species claims that fall within the scope of generic claims of Group A, by itself, such a genus-species relationship does not require the Groups to stand or fall together. It is quite common for genus and species to be separately patentable. In particular, it is often the case that even though a genus is unpatentable, species within the genus remain patentable. As set forth in the Brief there are many reasons that support the separate patentability of genus and species claims in this case.

The Examiner also states that Groups A and B should stand and fall together for purposes of issue 1 (enablement) because "claims 57-62 are in both Group A and Group B" (page 4 of the Examiner's Answer). Claims 57-62 are *multiply dependent* claims. The Brief clearly sets out that claims 57-62 are only included in Group A or B *to the extent that* they depend from base claims 37 (Group A) or 52 (Group B). The Examiner is rigorously correct that these claims are present in both Groups but, of course, this point is irrelevant. Different portions of the claims are present in each Group. The scope and content of the portions that are present in each Group differ and, for all of the reasons set forth in the Brief, the portions should stand or fall separately.

The Examiner further states that claims 37-39 should stand and fall together for purposes of issue 3 (indefiniteness) because "claims 38-39 depend from claim 37" (page 4 of the Examiner's Answer). Issue 3 addresses the definiteness of claims that include the language "substantially". As noted on page 4 of the Brief, claim 37 does *not* include this language (claims 38-39 do). In the Brief, Appellant submitted that the rejection was therefore improperly applied against claim 37 and that claim 37 should stand or fall separately from claims 38-39. The fact that claims 38-39 *depend* from claim 37 does not affect the logic of this outcome.

Argument

ISSUE 1: ***The pending claims are not invalid for lack of written description***

The claimed invention is a method of making a modified allergen which is less reactive with IgE. The method includes a step of preparing modified allergens that include at least one amino acid mutation in one or more IgE binding sites and a step of *screening* these modified allergens for IgE binding (i.e., steps (b) and (c) of claims 37 and 52). The method therefore *identifies* (i.e., makes) suitable modified allergens (and thus suitable mutations) by screening modified allergens with different mutations.

In the Answer, the Examiner articulates a breathtaking new written description standard for these claims. According to this Examiner, it is not possible to describe this method unless *all* suitable mutations (i.e., *all* mutations that reduce IgE binding) for *every* allergen are explicitly set forth in the application. Specifically, on several occasions in the Answer, the Examiner makes the following two statements:

> "With the exception of the *specific* method of making modified *peanut* allergen Arh 1 (sic), Ara h2, Ara h3, there is insufficient written description about which particular one or more amino acids within the full-length sequence of *all* protein allergen and *all* food allergen to (sic) be modified for the claimed method" (*emphasis* added, see pages 5 and 19).

> "Until the amino acids within the one or more IgE epitope (sic) of *all* protein allergen (sic) and *all* food allergen (sic) have been identified, the methods of making the modified allergen (sic) and food allergen (sic) are not adequately described" (*emphasis* added, see pages 5 and 19).

This is clearly not the law nor should it be. The whole point of the claimed method is to identify (i.e., make) suitable modified allergens by *screening* one or more modified allergens. The user does not know the identity of suitable mutations before practicing the screening method. As described in the Brief (and recently articulated in *University of Rochester*), such screening methods can be described without *any* description of compounds or proteins that can be identified by the method. Moreover, in the present case, the specification *does* contain extensive description of modified allergens that have been identified according to the claimed methods.

Appellant also notes that the Examiner seems to be improperly reading the preamble "method of *making*" language to impart a separate written description obligation. Thus, on page 19 of the Answer, the Examiner states that "the pending claims are drawn to a method *making*,

not a method of screening" and on page 16 that "in order to *make* a modified protein allergen [...] the particular one or more amino acids in one or more of the IgE binding sites [...] has to be identified". Appellant respectfully submits that the claims clearly recite a screening step. A skilled person would therefore recognize that the claims are drawn to a method of making *by screening*. However, Appellant would be willing to amend the claim preamble to read a "method of screening" or a "method of identifying" instead of a "method of making" if that would help resolve this issue.

For these and other reasons set forth in the Brief, the specification and case law clearly support Appellant's position that a skilled person would readily recognize that Appellant was in possession of the full scope of the claims. The rejection should be withdrawn.

ISSUE 3: ***Claims 37-39 are not indefinite for reciting the term "substantially"***

On page 21, the Examiner maintains her objection to Appellant's use of the term "substantially" in claims 38 and 39. Without providing any reasoning the Examiner states that the term is unclear since a modified allergen that exhibits 50% difference in T-cell activation (claim 38) or IgG binding (claim 39) would still have "substantially" the same properties as the unmodified allergen.

Appellant respectfully points out that those of ordinary skill in the art are expected to read and understand the terms "in substantially the same way" in context, and can evaluate when a modified allergen will qualify as having substantially the same properties if it exhibits 50% difference, and when it will not. Appellant further reiterates that the courts have clearly stated that terms such as "substantially" may be used in patent claims when warranted by the nature of invention, in order to accommodate the minor variations that may be appropriate to secure the invention. *Verve LLC v. Crane Cams*, 311 F.3d 1116 (Fed. Cir. 2002). Appellant relies on the Brief for further explication of this position.

ISSUE 4: ***Claims 37, 39-43, 46-47, 49-51 and 57-62 are not anticipated by Aki et al.***

On page 22, the Examiner maintains this rejection under 35 U.S.C. § 102(b). Appellant respectfully disagrees with the Examiner's arguments. In particular, Appellant reemphasizes that the *starting point* in the method of Aki et al. is not the dust mite allergen *Mag 1*, but a wholly artificial fusion protein which only includes a single IgE epitope of *Mag 1* (Mag1-E2, 10 amino acids) that has been extracted and then fused to β-galactosidase (1034 amino acids). This fusion

protein includes less than 1% of the original dust mite allergen *Mag 1* and a skilled person would readily recognize in light of the specification that it does not fall within the scope of the allergens of claim 37. A method that modifies this fusion protein cannot therefore anticipate the claimed methods.

The Examiner states on page 23 that "β-galactosidase is not a natural allergen [and] is merely a tool for purifying the recombinant allergen, very much like the histidine tag fused to the recombinant Ara h2 [in the present invention]". Appellant agrees that β-galactosidase is not a natural allergen and submits that this reinforces the differences that exist between the teachings of Aki et al. and the claimed invention. Appellant also respectfully submits that there is in fact a *substantial* difference between the β-galactosidase "fusion" of Aki et al. and the histidine tag "fusion" of the present invention. In the former case, a 10 amino acid IgE epitope is fused to a 1024 amino acid protein to yield a fusion protein that exhibits minimal identity (~ 1%) with the original dust mite allergen. In the latter case, a 100 amino acid natural allergen is fused to a 6 amino acid purification tag to yield a fusion protein that is substantially identical (~ 94%) to the original peanut allergen. A skilled person would readily recognize the significance of these substantial differences in the context of the present invention. For these and other reasons set forth in the Brief, Appellant respectfully submits that this rejection should be withdrawn.

ISSUE 6: ***Claims 37, 40-43, 48-53 and 57-62 are not anticipated by Burks et al.***

On page 24, the Examiner argues again that this rejection under 35 U.S.C. § 102(a) is proper. Appellant respectfully disagrees – it is an axiom of patent law that a prior art reference cannot be used to anticipate an invention if the teachings of that prior art reference were included in the patent application or the patent application properly claims priority to such an application. As noted in the Brief, the teachings of Burks et al. were included near *verbatim* in U.S. Serial No. 08/717,933 filed September 23, 1996 (see pp. 133-155 and the Figures referred to therein). The present application properly claims priority to this 1996 filing. Burks et al. was published after this priority date and cannot therefore be used as prior art under 35 U.S.C. § 102(a). Withdrawal of the rejection is earnestly requested.

ISSUE 7: ***Claims 37, 40-43, 48-53 and 57-62 are not anticipated by Stanley et al.***

On page 25, the Examiner argues that this rejection under 35 U.S.C. § 102(a) is also proper. Again, as noted in the Brief, the teachings of Stanley et al. were included near *verbatim*

in U.S. Serial No. 08/717,933 filed September 23, 1996 (see pp. 156-174 and 176-180). The present application properly claims priority to this 1996 filing. Stanley et al. was published after this priority date and cannot therefore be used as prior art under 35 U.S.C. § 102(a). Withdrawal of the rejection is earnestly requested.

Conclusion

For all of these reasons, Appellant respectfully submits that the pending claims are fully supported by the specification as filed and allowable over the art of record. The Examiner's rejections should be reversed.

Respectfully submitted,
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